McIndoe procedure for vaginal agenesis: Long-term outcome and effect on quality of life

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OBJECTIVE: The purpose of this study was to evaluate quality of life, sexual function, and long-term outcome in women after undergoing the McIndoe procedure for vaginal agenesis.

STUDY DESIGN: This was a retrospective descriptive study of patients who were treated with the McIndoe procedure for vaginal agenesis. Participants answered a structured questionnaire to describe self-reported outcomes in quality of life, sexual function and satisfaction, and body image after the McIndoe procedure. Patient characteristics along with short- and long-term findings were abstracted from the medical record. **RESULTS:** Eighty-six patients responded to the questionnaire. Average age (\pm SD) at surgery was 21 \pm 6 years (range, 12-49 years). The mean number of years (\pm SD) since surgery was 23 \pm 12 (range, 2-50 years). Seventy-nine percent of the respondents stated that the McIndoe procedure improved their quality of life. Ninety-one percent of the respondents were sexually active, with 75% able to achieve orgasm. Reported self-image was improved in 55% of the women.

CONCLUSION: The McIndoe procedure improves quality of life and sexual satisfaction and provides a functional vagina with minimal complications. (Am J Obstet Gynecol 2003;189:1569-73.)

Key words: Vaginal agenesis, McIndoe procedure, skin graft, quality of life

Uterovaginal agenesis (which usually is associated with normal fallopian tubes or tubule fimbriae, female karyotype, and complete differentiation of the ovaries) is known as Mayer-Rokitansky-Kuster-Hauser syndrome. External genitalia and secondary sex characteristics are normal in most cases. The syndrome may be associated with other embryogenic abnormalities, including urinary and skeletal defects. Despite the existence of countless theories, the primary cause of this syndrome remains unknown.

Treatment of vaginal agenesis is the development of a neovagina. Both operative and nonoperative techniques have been described. The aim of vaginoplasty is the formation of a vagina that will be satisfying in appearance, function, and feeling without excessive morbidity. Several methods are described in the literature, but there has been no consensus about an ideal approach. To date, a universal surgical technique has not been adopted. A common method has been the original Kirschner-Wagner² split-thickness skin graft method modified by McIndoe.³ This method has been criticized because of its

long hospital stay, risk of bowel and bladder injury, and vaginal stricture if not maintained.^{4,5} Advantages of nonsurgical methods include its simplicity, safety, avoidance of hospitalization, minimal morbidity, and ability to resort to operative techniques if this fails.⁴⁻⁹

At the Mayo Clinic, a modified McIndoe operation has been the method of choice to treat vaginal agenesis. ¹⁰ The published cumulative Mayo Clinic experience totals 225 patients from 1920 to 1985. ^{1,10-12} In this collection, 10% of women sustained complications including fistula, stricture, bleeding, prolapse, graft failure, or infection. No deaths that were related to the McIndoe procedure were observed. The cumulative series reported that 85% of women are able to have sexual intercourse with vaginal function described as "satisfactory." Contractures of the neovagina were seen in those women who ceased sexual activity or mold usage.

Ingram¹³ devised a modification of the nonoperative Frank technique using a bicycle seat to apply pressure to create a neovagina. He reported a 77% "favorable" experience in 26 patients who were treated with this technique and reported no ischemic necrosis or mucosal lacerations. Recently published nonoperative treatments for vaginal agenesis have noted similar results and few complications. Roberts et al⁹ reported on 37 patients who were treated with passive vaginal dilation. Ninety-two percent of the patients achieved anatomic and functional success. In a retrospective review, Alssandrescu et al¹⁴ reported on 201 women who were treated with

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Presented at the Twenty-Ninth Annual Meeting of the Society of Gynecologic Surgeons, Anaheim, California, March 5-7, 2003. Reprints not available from the authors.

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Table I. Operation performed after the McIndoe procedure

Type of procedure	N(n=71)
Vaginal vault prolapse*	3
Fistula repair†	2
Rectal prolapse	1
Laser vaporization of granulation tissue	1
Abdominal exploration‡	1
Urethral reconstruction	1
Surgery for stricture	1

^{*}Abdominal sacral colpopexy with mesh.

split-thickness skin grafting. Ten percent of the women had surgical complications, one half of which were graft/harvest site infections. They observed an anatomic success rate of 94%. Sexual satisfaction scored as "good" or "satisfactory" was seen in 72% of the women who completed a questionnaire.

Previous authors have reported on the ability to have vaginal intercourse and patient satisfaction after the creation of a neovagina. Our aim was to assess the perceived impact on quality of life, self-image, sexual function, and satisfaction after the McIndoe procedure in women with vaginal agenesis because of Mayer-Rokitansky-Kuster-Hauser syndrome. Complications and long-term follow-up are also reported.

Material and methods

Institutional review board approval was granted to investigate women who were treated for vaginal agenesis at the Mayo Clinic between January 1950 and January 2001. Surgical records of responding patients were reviewed. Medical charts were abstracted for survival, demographics, diagnosis, preoperative counseling, operative procedure, and immediate and long-term complications. The Survey Research Center assisted in developing a detailed descriptive questionnaire that covers 28 areas of interest. A survey was mailed to 213 eligible women. Patients reported their perceived change in self-image, body appearance, and quality of life after the McIndoe procedure. Thirteen questions were quantifiable statements that covered sexual behavior, orgasm, lubrication, coital bleeding, dyspareunia, past and current sexual activity, and patient and partner satisfaction. Additional scales were designed to characterize emotional support at the time of surgery. Information regarding graft/harvest site complaints, vaginal infections, incontinence, fistula formation, use of dilator/mold, and need for further surgery were compiled.

Results were summarized with the use of standard descriptive statistics: counts and percentages for categoric variables, and means, medians, SDs, and ranges

Table II. Findings at 1 year follow-up examination

Physical finding	N(n = 71)
Granulation tissue	39
Stricture	8
Discharge	5
Bleeding	3
Prolapse	3
Fistula	3

for continuous variables. Relationships among variables were tested for significance with the Pearson χ^2 test, the Fisher exact test, and Wilcoxon rank sum tests, as appropriate.

Results

Eighty-six of 213 patients (40%) responded to the in-depth questionnaire. Seventy-one charts of these 86 patients were available for review. The average age (\pm SD) of women who underwent the procedure was 21 \pm 6 years (range, 12-49 years). Ten women had undergone previous surgical procedures. Eight women attempted vaginal dilatation without success. The average number of years (\pm SD) since surgery was 23 \pm 12 (range, 2-50 years). At the time of survey, 14% women were single; 75% women were married or with a significant other, and 11% women were divorced or widowed.

The location of the harvest site was based on surgeon preference. Forty-seven grafts were taken from the buttock, 12 from the abdominal wall, 8 from the thigh, and 4 from the sigmoid colon. Mean operative time was 105 ± 51 minutes (range, 20-269 minutes). Mean $(\pm SD)$ change in postoperative hemoglobin was 1.7 ± 1.2 g/dL (range, 0.2 to 4.7 g/dL). Blood loss was not associated with previous dissection of the vaginal space (P = .5). No bladder injuries were reported; however, two bowel injuries required repair. One graft failure was treated with debridement and the placement of second graft. In the immediate postoperative period, there were five infections (one infection in the graft and four infections in the harvest site). All infections responded to debridement and intravenous antibiotics. Average length of hospital stay was 11 ± 3.2 days. There were no deaths as a result of the McIndoe procedure.

The 6-week postoperative examination revealed, on average a 94% graft take. Ten patients underwent further surgical repair at the Mayo Clinic (Table I). Two fistulas developed, one vesicovaginal and one rectovaginal. Both were treated successfully with operation. Urethral reconstruction was required in one patient with complete loss of the urethral floor. At 1-year follow-up, granulation tissue followed by strictures, discharge, bleeding, prolapse, and fistula were observed (Table II).

Fifty-five percent of women stated that their self-image was better after the McIndoe procedure. In addition, 62%

[†]One rectovaginal, one vesicovaginal.

[‡]Peritoneal inclusion cyst.

of the women noted that they were satisfied with overall body appearance after surgery. When asked if undergoing the McIndoe procedure changed their lives, 79% of the women responded with an overall improvement. No patient characteristic or surgical outcome was a statistically significant predictor of improved outcome in these three areas.

The goal of neovaginal creation is the formation of a satisfactorily functional vagina for intercourse. Ninety-one percent of the women were sexually active; 75% of the women were able to achieve orgasm. Sexual intercourse at least once a week was reported in 82% of women. Ninety-two percent of the women stated that they were satisfied with their sexual relationships. Eighty-three percent of the women reported being satisfied with their vaginal function during intercourse. Ninety percent of the women felt that their partners were satisfied with the function of the neovagina. A greater percent of women who used the mold postoperatively reported being sexually active after the procedure, compared with nonusers, although this was not statistically significant (P=.1).

Bleeding after intercourse was noted by 11% of the women. Twenty-nine percent of the women reported a lack of lubrication during intercourse most of the time. Thirteen percent of the women had dyspareunia during intercourse. Vaginal infections were perceived as a problem by 3% of the patients. Ten percent of the women reported daily loss of urine. Weekly fecal incontinence of any kind was noted in 4% of the women.

Dermatologic complaints of the harvest site were minimal. Eight percent of the women reported burning (an irritating pain sensation) in or around the site of harvested skin. This was equally distributed in all areas that were used for harvesting including thigh, buttock, or abdomen. Mild irritation (rash, sores, or peeling) was reported by 20% of women at or around the harvest site. Twenty-eight percent of the women responded that the harvest site was disfiguring. No statistically significant difference was seen between the location of the harvest site and a feeling of disfigurement ($P \ge .5$).

Seventy-three percent of the women stated that they wore the permanent mold >6 months after the procedure. Forty percent of the women commented that wearing the mold was a daily nuisance.

Most patients were sexually active after undergoing the McIndoe procedure. However, three patients were never sexually active because of the lack of a partner. Three women reported having no interest in sexual activity. Women who reported their vagina as nonfunctional were less likely to be sexually active (P = .007).

Twenty-eight percent of the women stated that, at the time of surgery, they were confused about the reason that they never developed a vagina. Seventy-four percent of the patient's mothers, 60% of fathers, and 41% of spouses

were supportive of the patient choosing surgery for vaginal construction.

Comment

Structural anomalies of the vagina and urogenital system are often challenging to diagnose and treat. Mullerian agenesis is second only to gonadal dysgenesis as a cause of primary amenorrhea. Although nonsurgical methods to treat vaginal agenesis are successful in creating a functional vagina, this is labor intensive and takes a motivated individual in a supportive environment. Furthermore, many patients are interested in immediate surgical intervention rather than the use of dilatation techniques that take several months and daily perseverance.

The results of our study demonstrate most of the patients who responded to our survey were sexually active and able to reach orgasm. More than 90% of these patients were satisfied with their sexual relationships, and 83% of them were satisfied with the function of their neovagina. These results confirm that an artificially created vagina can function well and allow women to develop intimate relationships.

It is difficult to assess the psychologic and emotional aspects of patients with structural abnormalities of the mullerian tract. How much of an impact surgical correction has on an individual's life when it comes to dating, interaction with others, and intimate relationships is unknown. Mobus et al¹⁵ surveyed 44 women after the operative correction of vaginal agenesis. They found that 61% displayed an impressive increase in self-esteem. They also found that women with a functionally dissatisfactory result had worse scores on self-esteem, attractiveness and self-confidence, and body accentuation-sensibility scales. They concluded that a successful operation leads to a reestablishment in female self-confidence, self-esteem, and sexual life.

We obtained patient-perceived changes in quality of life, body appearance, and sexual satisfaction after the McIndoe procedure with an in-depth questionnaire. Our goal was to gain more knowledge and understanding of what women face before and after the McIndoe procedure to better counsel them in their decision and help them deal with some of the feelings that they experience. Almost 80% of the women felt that the McIndoe procedure improved their quality of life. This supports the idea that vaginal function or lack of it plays a significant role in the establishment of self-confidence and self-esteem in young women. However, the creation of a functional vagina is only one part of the successful treatment. Surprisingly, nearly 30% of the women reported a lack of understanding about their diagnosis of vaginal agenesis. Because many patients were surveyed several years after their procedure, this may represent recall bias. Although thorough evaluation and counseling are carried out before surgical intervention, it is

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conceivable that the diagnosis might consume the patient's thoughts about the future that she will face knowing her ability to function as a "normal woman" might be impaired. This highlights the importance of preoperative counseling to help the patient understand the condition in regard to anatomy, physiology, the nature of the mullerian agenesis, reproductive consequences, and the long-term life style changes this may involve.

We acknowledge several limitations of our study. Only 40% of those women with vaginal agenesis who were treated with the McIndoe procedure responded to the questionnaire. Because of the intimate nature of the questions and the time since surgery for many patients, some women may not have felt it necessary or worthwhile to complete the questionnaire. It is conceivable that only those women with a favorable outcome responded to the questionnaire. However, our surgical results are in agreement with our previously published data on outcomes after the McIndoe procedure.

We developed a questionnaire to investigate specific areas of interest rather than using a validated questionnaire on sexual function and quality of life. One reason was that a standard questionnaire on sexual function does not take into account the uniqueness of women with vaginal agenesis who never had vaginal function before the creation of a neovagina. We wanted to describe our experience with the McIndoe procedure and report the patient's perceived attitudes toward the procedure and its effect on her life.

Correlation between vaginal depth and satisfactory outcome exist. ¹⁵ However, the functional success of the operation is not necessarily proportional to the length of the new vagina. ¹⁶ Vaginal dimensions by physical examination were not performed in our patients. Previously, we noted a tendency toward progressive contracture of the vagina if not coitally active or when a vaginal mold was not used. ¹⁰ Because this group represents patients at various stages of life, we felt the overall measure of success is whether the patient reported the ability to have vaginal intercourse to her satisfaction.

We feel that the McIndoe operation for vaginal agenesis offers women with mullerian agenesis a satisfactorily functioning vagina with minimal risk for minor treatable complications. This study has helped us better to understand the emotions that these young women are feeling and gives insightful information to assist in counseling women regarding long-term outcome and effects on quality of life.

Appropriate timing of the operation and patient's preparation and instruction likely enhance compliance, which is critical to success. Prospective studies that will use validated questionnaires and a multidisciplinary team are needed to confirm the long-term effects of the operative and the nonoperative creation of a vagina in women with vaginal agenesis.

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Discussion

DR ROBERT PORGES, New York, NY. The recorded experience of the Mayo Clinic with vaginal agenesis began in 1920. Institutional review board approval for the present study includes only the years from 1950 through 2000. Eighty-six of 213 women responded to a questionnaire, and of these, 71 patient records were available for review, which I believe may include some patients who were listed in previous reports from the clinic. The generally satisfactory results over such a span of time, by different operators, using different materials and different graft sites speak for the usefulness of the operative procedure, rather than the skill of any single operator, although we know that the operators involved over the last one-half century were all especially proficient. Could a less experienced gynecologist, doing perhaps one of these procedures every few years, still claim only a 10% complication rate?

The purpose of long-term follow-up in gynecology has its greatest usefulness in determining the pathophysiologic condition and efficacy of treatments for cancer. To a lesser extent, treatments that result of pelvic organ prolapse likewise deserve to be evaluated over more than several years. Whether a questionnaire probing the results that leads toward sexual satisfaction and quality of life